



Drug Enforcement Administration

[Docket No. DEA-947]

Bulk Manufacturer of Controlled Substances Application: Siegfried USA, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Siegfried USA, LLC. has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 8, 2021, Siegfried USA, LLC., 33 Industrial Park Road, Pennsville, New Jersey 08070-3244, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled Substance	Drug Code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Dihydromorphine	9145	I

Hydromorphenol	9301	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Phenylacetone	8501	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Methadone	9250	II
Methadone intermediate	9254	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium tincture	9630	II
Oxymorphone	9652	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substance in bulk for development of a new active pharmaceutical ingredient (API) and validation for a Drug Master File submission to the Food and Drug Administration. No other activity for this drug code is authorized for this registration.

Brian S. Besser,
Acting Assistant Administrator.